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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,644	03/29/2004	Jill M. Cielo	PC-1485	7628
23717 7590 10/31/2008 LAW OFFICES OF BRIAN S STEINBERGER 101 BREVARD AVENUE COCOA, FL 32922				
EXAMINER				
GHALL, ISIS A D				
ART UNIT		PAPER NUMBER		
1611				
MAIL DATE		DELIVERY MODE		
10/31/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/811,644

Applicant(s)

CIELO, JILL M.

Examiner

Isis A. Ghali

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 07/01/2008.

Claims 4-12 have been canceled.

Claims 1-3 and 13-14 are pending and included in the prosecution.

The following rejection has been overcome b virtue of applicant's amendment and remarks:

The rejection of claims 1-3 and 13-14 under 35 U.S.C. 112, second paragraph, as being indefinite.

The following rejection has been discussed in details in the previous office action, and is maintained for reasons of record:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US 2003/0007941 ('941), 2002/0119174 ('174), US 6,030,948 ('948), WO 96/25943 ('943) and US 6,376557 ('557).

US '941 teaches composition for treating hair loss and useful for treating different types of alopecia, the composition comprising carrier comprising water; up to 11.5% of the composition ammonium lauryl sulfate; 2-4%, sodium laureth sulfate; 2% cocamide MEA; 0.1% sodium chloride; 1-3% cocamidopropyl betaine; 0.5% fragrance (example C, page 16). Additionally, the reference disclosed the topical composition may contain propylene glycol (paragraph 0280), and urea (paragraph 0294).

US '941 does not teach tall oil, EDTA, methyl paraben, propyl paraben, disodium salts of sulfosuccinate, cocoamide DEA, alkyloxypolyethyleneoxyethanol, and sodium sulfate as claimed by claims 1 and 13.

US '174 teaches composition for regulating hair growth comprising pine oil (tall oil), EDTA, methyl paraben, propyl paraben, coconut monethanolamide (cocamide MEA) and coconut diethanolamide (cocoamide DEA), lactamide monethanolamine, disodium salts of sulfosuccinate and sodium sulfate (paragraphs: 0036, 0084, 0102, 0103, 0112, 0133, 0141, 0234, 0304, 0331, 0336, 0351).

US '948 teaches hair regeneration composition useful for treating alopecia comprising urea gel and alkyloxypolyethyleneoxyethanol (abstract; col.2, lines 47-50; table 4 at col.11).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition to treat hair loss comprising water; ammonium lauryl sulfate; sodium laureth sulfate; cocamide MEA; sodium chloride; cocamidopropyl betaine; propylene glycol, and urea as disclosed by US '941, and add the ingredients disclosed by US '174 comprising pine oil, EDTA, methyl paraben, propyl paraben, lactamide monethanolamine, disodium salts of sulfosuccinate, and sodium sulfate and further add alkyloxypolyethyleneoxyethanol disclosed by US '948 motivated by the teaching of US '174 and US '948 that composition comprising such ingredients are useful to regulate hair growth and treat alopecia, as desired by US '941, with reasonable expectation of having composition comprising all the above ingredients disclosed by the three references in one composition, wherein the composition effectively useful to treat hair loss and regeneration and regulate hair growth in person suffering from alopecia.

The combination of the references does not teach the exact amounts of some ingredients as instantly claimed. However, the claimed amounts do not impart patentability to the claims, absent evidence to the contrary.

The combination of US '941, US '174 and US '948 does not teach enzymes as claimed by claims 1-3, 13-14.

WO '943 teaches composition to stimulate hair follicles and hair growth, wherein the composition comprises enzymes trypsin (protease) and dispase (lipase) in effective amounts to enhance the penetration of the individual components in the hair growth

composition through intact skin. The amount of enzymes is less than 1% (abstract; page 16, first two paragraphs).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide hair growth generation composition comprising the ingredients disclosed by the combination of US '941, US '174 and US '948, and further add trypsin and dispase enzymes disclosed by WO '943 because WO '943 teaches enzymes enhance the penetration of the individual components in the hair growth composition through intact skin, with reasonable expectation of having composition stimulating hair growth that comprises enzymes that effectively enhance the penetration of the individual components in the hair growth composition through intact skin to achieve enhanced successful hair growth stimulation.

Although the combination of US '941, US '174 and US '948 teaches composition comprising urea, however, the combination does not explicitly teach diazolidinyl urea as claimed by claims 1 and 13.

US '557 teaches hair growth promoter composition useful to treat alopecia and comprising diazolidinyl urea that has effective anti-bacterial and preservative action on the composition (abstract; col.8, lines 3-7).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide hair growth generation composition comprising the ingredients disclosed by the combination of US '941, US '174 and US '948, and further add diazolidinyl urea disclosed by US '557 because US '557 teaches diazolidinyl urea has effective anti-bacterial and preservative action on the hair growth promoter

composition, with reasonable expectation of having composition to promote hair growth that comprises diazolidinyl urea that provides effective anti-bacterial and preservative action on the composition to achieve stable hair growth composition.

Response to Arguments

3. Applicant's arguments filed 07/01/2008 have been fully considered but they are not persuasive.

Applicant argues that claims 1 and 13 as amended include a composition that is "consisting essentially of", which the applicant has found to be a novel invention for "reducing hair loss and promoting hair life".

In response to this argument, it is argued that the expression "consisting essentially of" limits the scope of the claim to the specified ingredients, and those that do not materially affect the basic and novel characteristics of the composition. *In re Janakirama-Rao*, 317 F 2d 951, 137 USPQ 893 (CCPA 1963). When applicant contends that modifying components in the reference's composition are excluded by the recitation of "consisting essentially of", applicant has the burden of showing the basic and novel characteristics of the claimed composition, i.e. showing that the introduction of these components would materially change the characteristics of applicant's composition. *In re De Lajarte*, 337 F 2d 870, 143 USPQ 256 (CCPA 1964).

Applicant argues that the rejections is loose at it combines five references which together do not describe, teach or suggest the novel "composition" of the subject

claims. Applicant disagrees with the office action statement that the claimed amounts do not impart patentability to the claims. Applicant discovered the unique composition which included numerous testing and the novel results which followed which are described to on pages 8+ of the subject specification.

In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

It is further argued that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. See *In re kerkhoven* 205 USPQ 1069, 1072; *In Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945); *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80) 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by the cited references that these substances are used in compositions to improve hair conditions, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to reduce hair loss and promote hair life. Therefore, the artisan would have been motivated to combine the disclosed ingredients into a single

composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

Regarding the claimed amounts, even if the references do not specifically teach adding the ingredients in the amounts claimed by applicant, it is argued that the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Applicant argues that where a reference is relied on to support a rejection, whether or not in a minor capacity, that reference should be positively included in the statement of the rejection.

In response to this argument, the examiner carefully reviewed the rejection and does not find any reference relied upon that is not included in the statement of the rejection. The examiner relied on US '941, US '174, US '948, WO '943 and US '557, and all of them are positively included in the body of the rejection.

Applicant argues that the mere fact that someone in the art can rearrange parts of a reference device to meet the terms of a claim is not by itself sufficient to support a finding of obviousness. Applicant argues that there is no teaching, nor suggestion for modifying the references of record to include all the novel features of the amended claims, and no reasonable expectation of success found in the prior art.

In response to this argument, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one having ordinary skill in the art would have added the ingredients of US '174 and US '948 to composition disclosed by US '941 because both of US '174 and US '948 teaches composition comprising ingredients useful to regulate hair growth and treat alopecia, as desired by US '941. Further, one having ordinary skill in the art would have added enzymes taught by WO '943 because WO '943 teaches that enzymes enhance the penetration of the individual components in the hair growth composition through intact skin. Additionally one having ordinary skill in the art would have replaced urea taught by US '948 by diazolidinyl urea disclosed by US '557 because US '557 teaches diazolidinyl urea has effective anti-bacterial and preservative action on the hair growth promoter composition. Therefore, motivation to combine the references does exist as

well as reasonable expectation of success provided by the advantage of each reference.

Applicant argues that "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.

It has been held that: "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative

steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR

INTERNATIONAL CO. v. TELEFLEXINC. ET AL. (2007).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611